

micro particles being further characterized by a surface having at least a minimum amount of roughness;
the micro particles having an average particle size generally above 80 microns and up to 3000 microns with a surface roughness of 10 angstroms or more;
wherein relative average particle size and average roughness of texture alone are sufficient in combination to, in an autogenous manner, substantially preclude migration of the particles from an augmentation site.

C1
(cont.)

REMARKS:

In accordance with the above amendments, the original Claims 1-50 of the parent application have been canceled, without prejudice, and a new slate containing Claims 51-79 have been presented for examination. It is believed that the new Claims present more clear and concise language with regard to the invention and overcome certain rejections under 35 U.S.C. § 112, second paragraph, applied to certain Claims in the parent application.

In the parent application, Claims of the scope presented herein were rejected under 35 U.S.C. § 103 as being unpatentable over the combination of Törmälä et al (U.S. Patent 4 863 472) in view of Nashef et al (U.S. Patent 4 678 470). In this combination, Törmälä et al are deemed to disclose micro particles encompassed by the claims of the present invention and Nashef et al, to teach the

use of a physiological carrier or vehicle thereby, in combination, rendering the rejected Claims unpatentable.

Each of the independent Claims presently pending contains language defining the micro particles in terms of being generally soft, malleable and having elastic or resilient properties in line with their use for long-term augmentation of soft tissue. This represents a material quite different from the materials contemplated by the cited prior art references, Törmälä et al and Nashef et al. All of the particulate matter utilized in the bone grafting associated with the disclosures of the two combined references is decidedly of hard, brittle and non-malleable materials. They are specifically designed to replace bone rather than soft tissue and, accordingly, do not possess the physical characteristics required by the present Claims. The present claims are believed to clearly preclude the materials of the invention disclosed by Törmälä et al and any invention suggested by the combination of Törmälä et al and Nashef et al.

A further point raised by the Examiner with respect to particle retention or containment involves the orifice associated with the casing of Törmälä et al. It is believed that the Examiner's conclusion does not represent a fair interpretation of the reference and so that conclusion is respectfully traversed.

It is submitted that the orifice described in column 2, lines 44-59 of Törmälä et al, in fact, does not allow the bone

graft powder particles to migrate at all as the Examiner suggests, but only to contact the bone. Only the part of the supporting structure located against the bone surface contains the one or more orifices whose size is bigger than the size of the bone graft powder particles. The orifice or orifices clearly only allow the particles to contact the bone tissue at the site of the graft and does not permit any type of migration away from the site. It is further noted that the description of the structure of the casing of Törmälä et al, beginning at line 38 of column 2, reads as follows:

" . . . The bone graft powder is located inside and/or below this supporting structure and this supporting structure includes such open porosity, which allows the surrounding tissues to grow through the supporting structure but which prevents the migration of the bone graft powder through the pores outside the supporting structure. . . ." (Emphasis added)

In this manner, the bone graft powder of Törmälä et al is free only to move through the orifice into contact with the bone. Applicants believe that this clearly is not equivalent to or even close to the non-retentive nature of the micro-implantation system of the present invention.

Applicants believe that the remarks presented herein may be helpful in more clearly describing the differences between the

cited art and their invention. Substantial differences are seen both in the nature of the particles used and in the autogenous retention feature of the applicants' system. They believe that they are responsible for contributing a decided breakthrough with respect to the long-term augmentation of soft tissue, particularly with materials that mimic the malleability and resilience of the tissue augmented.

Applicants believe that the above amendments, together with the remarks contained herein, render the present Claims patentably distinct from the combination of references applied and with respect to any references known to them used either singularly or in combination. Entry of the present amendments, reconsideration and early allowance of all of the Claims is respectfully requested.


Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing letter and Preliminary Amendment A for Application Filed under 37 CFR 1.60, in application Serial No. 08/052,414, filed on April 22, 1993, of Robert A. Ersek et al entitled "TEXTURED MICRO IMPLANTS" is being sent by facsimile transmission to: Attention: Examiner D. Brittingham, Art Unit 3308, The Commissioner of Patents and Trademarks, Washington, D.C. 20231, on October 19, 1993.


Christine M. Zumbalda
Secretary to C.D. G. Mersereau

Date of Signature: October 19, 1993

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